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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/699,487 | 10/31/2003 | David M. Hardin | 10000/212 | 3147 |
| 757 | 7590 | 12/28/2004 | EXAMINER | |
| BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610 | | | KASZTEJNA, MATTHEW JOHN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3739 | |

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/699,487 | HARDIN ET AL. | |
| | Examiner Matthew J Kasztejna | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 31 October 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Claim Objections

1. Based upon the specification, the applicant apparently meant the first outer member is slideably disposed on the proximal end of the inner handle member, rather than on the distal end of the inner member as stated in claim 1. For examination purposes, it is assumed first outer handle member is slideably disposed on the proximal end of the inner handle member.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5-6, 8, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 5-6, 8, 14 and 16 recite the limitation "second outer handle member". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,579,279 to Rabiner et al.

In regards to claim 1, Rabiner et al. disclose a handle 20 for a medical device, comprising: an inner handle member 40 having proximal and distal ends; a first outer handle member 42 slideably disposed on the proximal end of the inner handle member; an elongate sheath 26 attached to the inner handle member and axially extending beyond the distal end, the sheath defining a sheath lumen; and a stylet 29 attached to the first outer handle member and disposed in the sheath lumen (see Figs. 1 and 2).

In regards to claim 2, Rabiner et al. disclose a handle 20 for a medical device further comprising a connector 124 on the second outer handle member 22, the connector having adaptations to connect the handle to a medical device (see Fig. 2).

In regards to claim 3, Rabiner et al. disclose a handle 20 for a medical device wherein the inner handle member define a handle lumen 52 (see Col. 4, Lines 55-58).

In regards to claim 4, Rabiner et al. disclose a handle 20 for a medical device wherein the stylet is disposed in the handle lumen and extends into the sheath lumen (see Fig. 2).

In regards to claims 5-6, Rabiner et al. disclose a handle 20 for a medical device further comprising a means 44 for fixing an axial position of the inner handle member relative to the second outer handle member, wherein the means for fixing comprises an engaging member 132 extending through a thickness of the second outer handle member (see Col. 6, Lines 13-24).

In regards to claims 8-10, Rabiner et al. disclose a handle 20 for a medical device further comprising a stop 44 on the inner handle member the limits axial

movement of the inner handle member relative to the second outer handle member, wherein the stop comprises a circumferential projection (see Figs. 1 and 2).

In regards to claims 11-12, Rabiner et al. disclose a handle 20 for a medical device further comprising a first series of graduations 182 on the inner handle member, and wherein the graduations correspond to a predetermined length by which the stylet extends axially beyond the distal end of the sheath (see Col. 7, Lines 30-42).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 25 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al.

In regards to claims 22, 25 and 27-28, Flaherty et al. disclose a handle for a medical device comprising: an inner handle member; a first 68 and second 70 outer handle members slideably disposed on the inner handle member; an elongate sheath 12 attached to the inner handle member and defining a sheath lumen; a stylet 14 attached to the first outer handle member and disposed in the sheath lumen; and a series of graduations 60 disposed on the inner handle member, each graduation of the series of graduation corresponding to a predetermined length by which the stylet extends beyond a distal end of the sheath (see Col. 10, Lines 23-44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 6,579,279 to Rabiner et al. in view of U.S. Patent No. 6,524,259 to Baxter-Jones et al.

In regards to claim 7, Rabiner et al. disclose a handle 20 for a medical device comprising a means 44 for fixing an axial position of the inner handle member relative to the second outer handle member but is silent with respect to the engaging member comprising a thumbscrew. Baxter-Jones et al. teach of an analogous handle having a locking mechanism 124 including a locking knob 110 (see Col. 9, Line 49 – Col. 10, Line 31). It would have been obvious to one skilled in the art at the time the invention was made to use a thumbscrew as a means for fixing the inner handle member in the apparatus of Rabiner et al. in order to secure an inner member with respect to an outer cover as taught by Baxter-Jones et al. and is well-known in the art.

6. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,579,279 to Rabiner et al. in view of U.S. Patent No. 5,611,778 to Brinon.

In regards to claims 13-14, Rabiner et al. disclose a handle 20 for a medical device further comprising a first series of graduations 182 on the inner handle member, and wherein the graduations correspond to a predetermined length by which the stylet extends axially beyond the distal end of the sheath but is silent with respect to a second series of graduations on the inner handle member which correspond to a predetermined

second length by which the sheath extends axially beyond a distal end of the second outer handle member. Brinon teaches of an analogous surgical instrument having a set of auxiliary axial marks 220 (see Col. 2, Lines 1-12 and Col. 3, Lines 35-53). It would have been obvious to one skilled in the art at the time the invention was made to include a second set of graduation on the inner handle member in the apparatus of Rabiner et al. in order to provide a second set of markings which will indicate the length the stylet extends from a distal end, as taught by Brinon.

7. Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,579,279 to Rabiner et al. in view of U.S. Patent No. 6,283,951 to Flaherty et al.

In regards to claims 15-21, Rabiner et al. disclose a handle 20 for a medical device, comprising: an inner handle member 40 having proximal and distal ends; a first outer handle member 42 slideably disposed on the proximal end of the inner handle member; an elongate sheath 26 attached to the inner handle member and axially extending beyond the distal end, the sheath defining a sheath lumen; and a stylet 29 attached to the first outer handle member and disposed in the sheath lumen but is silent with respect to a slideable member 58 disposed on the inner handle member and adapted to be locked on the inner handle member. Flaherty et al. teach of an analogous device having a control and/or locking mechanism 58 is located on the handle 50 that includes a needle thumb slide 68 and an adjustable needle stop 70 that cooperatively slide along a graduated region 60 of the handle 50. The needle thumb slide 68 may be directed axially along the graduated region 60 to deploy the puncturing

element 14, as described more particularly below. The adjustable needle stop 70 is slidable on the handle 50 and is securable at a plurality of positions on the graduated region 60 of the handle 50. Thus, the adjustable needle stop 70 may be locked at a first position on the graduated region 60, loosened, directed axially to a second position on the graduated region 60, and locked at the second position to limit the movement of the needle thumb slide 68, and consequently the depth of penetration of the puncturing element 14 (see Col. 10, Lines 23-44). It would have been obvious to one skilled in the art at the time the invention was made to include a slidable locking mechanism in the apparatus of Rabiner et al. in order to variably limit the depth of penetration of the stylet as taught by Flaherty et al.

8. Claims 23-24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,283,951 to Flaherty et al. in view of U.S. Patent No. 5,611,778 to Brinon.

In regards to claim 23-24 and 29, Flaherty et al. disclose a handle for a medical device comprising: an inner handle member; a first 68 and second 70 outer handle members slideably disposed on the inner handle member; an elongate sheath 12 attached to the inner handle member and defining a sheath lumen; a stylet 14 attached to the first outer handle member and disposed in the sheath lumen; and a series of graduations 60 disposed on the inner handle member, each graduation of the series of graduation corresponding to a predetermined length by which the stylet extends beyond a distal end of the sheath but is silent with respect to a second series of graduations on the inner handle member which correspond to a predetermined second length by which

the sheath extends axially beyond a distal end of the second outer handle member.

Brinon teaches of an analogous surgical instrument having a set of auxiliary axial marks 220 (see Col. 2, Lines 1-12 and Col. 3, Lines 35-53). It would have been obvious to one skilled in the art at the time the invention was made to include a second set of graduation on the inner handle member in the apparatus of Flaherty et al. in order to provide a second set of markings which will indicate the length the stylet extends from a distal end, as taught by Brinon.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,283,951 to Flaherty et al. in view of U.S. Patent No. 6,579,279 to Rabiner et al.

In regards to claim 26, Flaherty et al. disclose a handle for a medical device but is silent with respect to the medical device comprising an endoscope. Rabiner et al. teach of an analogous device wherein a medical device such as an endoscope may be received within the catheter for movement relative thereto (see Col. 2, Lines 39-44). It would have been obvious to one skilled in the art the time the invention was made to use an endoscope in the apparatus of Flaherty et al. in order to provide a tool for observation of an internal site as taught by Rabiner et al. and is well known in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK

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12/17/04

Beverly M. Flanagan
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PRIMARY EXAMINER